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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/663,306	09/15/2000	Zhong Zhong	ORT1296	2391

7590 03/11/2003

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EXAMINER

CARLSON, KAREN C

ART UNIT	PAPER NUMBER
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1653

DATE MAILED: 03/11/2003

13

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/663,306

Applicant(s)

ZHONG ET AL.

Examiner

Karen Cochrane Carlson, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 November 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-85 is/are pending in the application.
- 4a) Of the above claim(s) 1-81 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 82-85 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

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This Office Action is in response to Paper #12, filed November 13, 2002. Claims 1-85 are currently pending. Claims 1-81 are withdrawn from further consideration by the Examiner because these Claims are drawn to non-elected inventions. Claims 82-85 are currently under examination.

Withdrawal of Objections and Rejections

The rejection of Claims 82-85 under 35 U.S.C. 112, second paragraph, is withdrawn.

Maintenance of Notations, Objections and Rejections

Note again to Applicants: The IDS filed January 29, 2001 (Paper 34) states that there are 3 sheets of references cited -see top wherein the statement "Sheet 1 of 3" is found. However, sheets 2 and 3 are not found in the application, and sheet 1 appears to list all of the submitted references.

This application has been filed with informal drawings which are acceptable for examination purposes only. Formal drawings will be required when the application is allowed.

The disclosure is again objected to because of the following informalities: The text of Example 4 is not complete.

Appropriate correction is required.

Applicants have not addressed the above three notations and objection.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 82-85 are again rejected under 35 U.S.C. 102(b) as being anticipated by Mazer et al. (USP 5,698,222; issued December 6, 1997). Mazer et al. teach a calcium supplement (Claims 82, 84) in a pharmaceutical formulation (Claims 83, 85).

Claims 82 and 84 are drawn to transcription factor regulators, formally referred to as compounds, that activate protease to cleave a membrane bound constitutively active transcription.

At page 17-18 of the specification, a fusion protein comprising of a strong transcription activator and a dominant membrane localization sequence comprising a protease cleavage site is cleaved by the protease calpain, which cleaves the fusion protein and releases the strong transcriptional activator from the membrane to activate protein expression. Calpain activity is stated to be strictly dependent on calcium. Therefore, calcium is a compound (or transcription factor regulator) that stimulates the activity of a protease to release a transcription factor from the membrane.

Applicants argue that each and every element of the claim must be either expressly or inherently present in a single art prior reference to be anticipated by the reference. Applicants assert that because Mazer et al. do not teach that their calcium supplement will activate a protease that will cleave a protease cleavage site found in a membrane-bound transcription factor, this calcium supplement cannot anticipate the claims. A patent will not be granted on a known compound, whether this known compound has been identified in a different manner or used in a different manner from that taught in the prior art. There is sufficient evidence that the product disclosed by the reference is Applicants' product, and the burden is shifted to

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Applicants to distinguish the two. See *In re Best*, 195 USPQ 430 and *Ex Parte Gray* 10 USPQ 2d 1922, 1923. Therefore, this argument is not persuasive.

No Claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

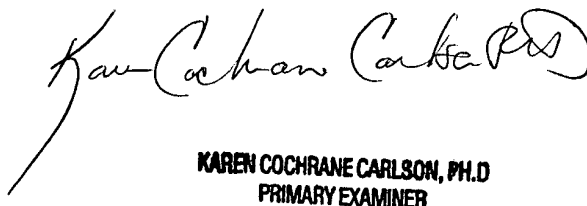
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen Cochrane Carlson, Ph.D. whose telephone number is 703-308-0034. The examiner can normally be reached on 7:00 AM - 4:00 PM, off alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Christopher Low can be reached on 703-308-2329. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

March 5, 2003


KAREN COCHRANE CARLSON, PH.D
PRIMARY EXAMINER